IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

JEFFREY D. FISHER, Individually and on Behalf of All Others Similarly Situated,	)	
Plaintiff,	)	
v.	)	1:22-CV-115
FENNEC PHARMACEUTICALS INC., ROSTISLAV RAYKOV, and ROBERT ANDRADE,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Catherine C. Eagles, District Judge.

The defendants Fennec Pharmaceuticals, Inc. and two of its officers, CEO Rostislav Raykov and CFO Robert Andrade, move to dismiss this securities fraud class action brought by the plaintiff Jeffrey D. Fisher for failure to state a claim. Because the complaint does not adequately plead actionable statements or omissions or scienter under the applicable heightened pleading standards, the motion will be granted. The defendants' motions to consider and to take judicial notice are denied, as it is unnecessary to consider these materials to grant the defendants' substantive motion.

I. Allegations in the Complaint

Mr. Fisher bought stock in Fennec while Fennec's application for approval of a new prescription drug was pending with the Food and Drug Administration. *See* Doc. 24 at ¶¶ 22, 7–16. He contends that in its public statements about this process beginning on

May 28, 2021, Fennec misled investors about the likelihood the application would be approved. *Id.* at ¶¶ 2–3. These misrepresentations and omissions, he contends, violated § 10(b) of the Exchange Act and a related regulation known as Rule 10b-5. *Id.* at ¶ 18.

A. Fennec and Pedmark

Fennec is a biotech company with its principal place of business in Research Triangle Park, North Carolina. Doc. 24 at ¶¶ 1, 23. The company's main focus is the development of the new drug known as Pedmark, a formulation of sodium thiosulfate that purports to prevent hearing loss in children undergoing certain types of chemotherapy treatment. *Id.* at ¶¶ 1, 48. Because Pedmark is a new pharmaceutical drug, the FDA requires Fennec to seek and obtain approval for Pedmark through the FDA's New Drug Application (NDA) process before Fennec can sell, market, and distribute Pedmark for commercial use in the United States. *Id.* at ¶ 32.

B. New Drug Application Process Generally

The NDA process provides the FDA with the information it needs to determine whether the drug is safe and effective, its benefits outweigh its risks, its proposed labeling is appropriate, and "the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity." *Id.* As part of this process, drug sponsors such as Fennec must make a detailed showing about "Chemistry, Manufacturing and Controls" for the drug and the manufacturing facility so "that pharmaceutical drug products are consistently effective, safe and high quality for consumers." *Id.* at ¶ 34. If a sponsor changes its drug

manufacturer, it must demonstrate to the FDA that the change will not adversely impact the quality, safety, and efficacy of the drug. *Id.* at ¶ 35.

As part of the NDA process, the FDA will monitor the manufacturer of the drug and conduct a pre-approval inspection of the facilities to assess readiness for commercial manufacturing and conformance to the application, as well as to conduct a data integrity audit. *Id.* at ¶¶ 41–43. At the end of the inspection, FDA inspectors will conduct an exit interview to explain any observed violations of FDA standards. *Id.* at ¶ 44. They also memorialize these violations in a Form 483 issued to the manufacturing facility. *Id.* The Form 483 is not a final decision, and facility management has 15 days to provide written responses to the Form 483 observations. *Id.* at ¶¶ 46–47.

If the FDA does not approve an NDA, it will send the sponsor a Complete Response Letter (CRL), "which describes all the specific deficiencies that the FDA identified in the NDA and when possible, recommends actions that the sponsor could take to place its NDA in condition for approval." *Id.* at ¶ 47. After receiving a CRL, the sponsor may resubmit its NDA. *Id.*

C. Pedmark's NDA

In December of 2018, Fennec filed an NDA with the FDA for Pedmark. *Id.* at ¶ 52. Fennec contracted with Pharmaceutics International, Inc. (PII) to manufacture Pedmark. *Id.* at ¶ 53. PII had been on the receiving end of several negative regulatory findings by European regulators in 2016, who had "prohibited PII from shipping drugs to Europe" because of manufacturing deficiencies. *Id.* at ¶ 54. And in October of 2016, one

pharmaceutical company recalled 43,000 bottles of a drug produced by PII because of "failed stability testing for impurity levels." *Id.*

In July 2020, FDA inspectors issued a Form 483 for both of PII's facilities "while it was under contract as Fennec's drug product manufacturer for" Pedmark. *Id.* at ¶ 55. The FDA saw deficiencies in PII's equipment maintenance, building conditions, and the prevention of microbiological contamination, among other things. *Id.* at ¶ 56.

In August 2020, the FDA issued a CRL for the Pedmark NDA. *Id.* at ¶ 57. According to Fennec's announcement, the FDA did not approve the drug because of the manufacturing deficiencies identified in a Form 483, *id.*, and no concerns about the drug's safety or efficacy were identified. *See id.* at ¶¶ 5, 57. Because the problems with Pedmark's NDA were manufacturing-related and not a result of concerns over efficacy or side effects, analysts were generally positive about Fennec's stock price. *See id.* at ¶¶ 67–68.

Some nine months after the CRL letter, Fennec resubmitted the Pedmark NDA, and, in the first statement at issue in this litigation, Fennec announced the resubmission on May 28, 2021. *Id.* at ¶ 69.[1] Fennec made generally optimistic statements through a press release about efforts to resolve the manufacturing issues that led to the CRL in August 2020 and about Fennec's progress toward receiving NDA approval. *See id.* (general optimistic statements on May 28). Fennec and Mr. Raykov repeated generally

[1] Statements made earlier are not at issue in this lawsuit. *See generally, Chapman v. Fennec Pharm. Inc.*, No. 20-CV-812, Docs. 30, 48, 57.

optimistic public statements on June 22, *id*. at ¶ 72, and August 10. *Id*. at ¶¶ 82–83, 85–86. Over the early summer of 2021, Fennec's stock price went up. *Id*. at ¶¶ 70, 73.

On August 11, Mr. Raykov again repeated these generally positive statements. *See id*. at ¶¶ 89–91. He also affirmatively asserted his belief that the manufacturing deficiencies had been addressed and that Fennec's "quality department" believed the facility was ready for resubmission, *id*. at ¶ 89–90, but he qualified that by telling investors that Fennec had a back-up plan for another manufacturer if that turned out not to be the case. *Id*. at ¶ 91. Beyond these general statements, he said that "I really don't want to get into the details about the pre-approval proof of inspection because you create expectations." *Id*.

On September 22, Mr. Raykov again made public statements about the NDA. He led with the observation that that "[y]ou never want to be overly confident with anything when it comes to the FDA." *Id*. at ¶ 93. But his statements were generally optimistic that the NDA would be approved, and he specifically said that the plant had made "significant improvements." *Id*. He repeated Fennec's belief that "we think the plant is in good shape to refile," and stated "we did not do this in a vacuum, we did this based on communication from the plant, we did this in speaking with the FDA on a regular basis." *Id*. He asserted that Fennec "expect[ed] approval early next year." *Id*. at ¶ 94.

The FDA inspected PII facilities on unspecified dates between July 26 and September 29. *Id*. at ¶ 75. On September 29, PII provided Fennec with the Form 483 issued by the FDA documenting its inspections, as well as the FDA's audit inspection report, also called an EIR. *Id*. at ¶¶ 79–80. These documents identified numerous

violations of good manufacturing practices, including cracked vials, unsterilized manufacturing suites, and improper glove protocol; some vials of Pedmark were left unsecured and uncapped during a fire alarm. *Id.* at ¶ 76.

In public statements issued on September 29, Mr. Raykov was noticeably less optimistic, though he continued to express hope that the NDA would be approved. *Id.* at ¶ 96. He referenced the possibility of an EIR and implied that FDA inspections had resulted in some negative observations though he did not say so directly; he did affirmatively state that "those observations are not critical, so that this plant can pass" inspection. *Id.* He repeated that if the plant did not pass inspection, Fennec had a second manufacturer so that it could file another NDA after a short delay. *Id.*

On November 10, Fennec made general statements in a press release that it was spending money on "essential activities in preparation for the launch of" Pedmark. *Id.* at ¶ 98. It made no mention of any problems at the manufacturing facility or of any recent inspections by the FDA. *See id.* at ¶¶ 98–99. In an SEC filing the same day, it mentioned a "constructive and collaborative" meeting with the FDA about the 2020 CRL issued after Fennec's first NDA. *Id.* at ¶ 101.

Mr. Fisher bought Fennec stock on November 23. Doc. 16-4 at 4. On November 30, Fennec announced that it received another CRL from the FDA for the Resubmitted Pedmark NDA which "was issued as a result of identified manufacturing deficiencies which need to be satisfactorily resolved before the Pedmark NDA can be approved." Doc. 24 at ¶ 110. As a result of the CRL news, Fennec's stock price dropped

significantly. *Id.* at ¶ 112. The FDA had not approved Pedmark at the time Mr. Fisher filed the operative complaint.[2]

II. Jurisdiction

The Exchange Act gives the district courts of the United States "exclusive jurisdiction" of violations of the Exchange Act "or the rules and regulations thereunder." 15 U.S.C. § 78aa(a). Because Mr. Fisher asserts claims under §§ 10(b) and 20(a) of the Exchange Act, this Court has jurisdiction.

III. The Elements

To make out a claim for fraud under § 10(b), a plaintiff must adequately plead "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, Inc.*, 552 U.S. 148, 157 (2008). "Scienter" in this context is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 319 (2007) (citation omitted).

"Section 20(a) of the Exchange Act imposes liability on each person who controls any person liable under any provision of this chapter or of any rule or regulation thereunder." *KBC Asset Mgmt. NV v. DXC Tech. Co.*, 19 F.4th 601, 614 n.4 (4th Cir.

[2] The defendants have recently filed a second request for judicial notice, asking the Court to take notice of a recent FDA press release announcing that Pedmark has been approved. Doc. 35. The Court does not need to take judicial notice of this press release to rule on the motion to dismiss, so the motion is denied.

2021) (cleaned up); *accord* 15 U.S.C. § 78t(a). To make out a claim under § 20(a), then, Mr. Fisher must first make out a claim under § 10(b).

IV. The Heightened Pleading Standards

Allegations of securities fraud must meet the heightened pleading standards of Federal Rule of Civil Procedure 9(b), requiring that plaintiffs alleging fraud (of any kind) "must state with particularity the circumstances constituting fraud," and of the Private Securities Litigation Reform Act of 1995 applicable to claims brought under § 10(b).[3] "The PSLRA provides that in pleading a material misrepresentation or omission, in violation of § 10(b) of the Exchange Act and Rule 10b-5, and the scienter necessary to such a misrepresentation or omission, the plaintiff must plead *facts*." *Teachers' Ret. Sys. of LA v. Hunter*, 477 F.3d 162, 172 (4th Cir. 2007). If the complaint does not meet these heightened pleading requirements, it shall be dismissed "on the motion of any defendant." 15 U.S.C. § 78u-4(b)(3)(A); *see, e.g.*, *Chapman v. Fennec Pharms. Inc.*, No. 20-CV-812, 2021 WL 7209981 (M.D.N.C. Dec. 16, 2021) (Mag. J., Order and Recommendation), *adopted* 2022 WL 613378 (M.D.N.C. Mar. 2, 2022).

As to scienter, the complaint must "state with particularity facts giving rise to a strong inference that defendant acted with" an "intent to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 314, 319 (2007). Negligence is not sufficient; to plead scienter a plaintiff must show intentional

[3] The PSLRA was enacted "to prevent Securities Exchange Act claims from being employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." *Singer v. Reali*, 883 F.3d 425, 439 (4th Cir. 2018) (cleaned up).

misconduct or recklessness "so highly unreasonable and such an extreme departure from the standard of ordinary care as to present a danger of misleading the plaintiff to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Matrix Cap. Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 181 (4th Cir. 2009) (citation omitted).

"[R]aising a 'strong inference' of scienter is no small burden." *Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 624 (4th Cir. 2008) (citation omitted). Courts "determining whether the pleaded facts give rise to a strong inference of scienter . . . must take into account plausible opposing inferences." *Tellabs*, 551 U.S. at 323 (cleaned up). A complaint adequately pleads scienter when, based on the alleged facts, the inference of scienter is "more than merely reasonable or permissible," *Johnson v. Pozen Inc.*, No. 7-CV-599, 2009 WL 426235, at *13 (M.D.N.C. Feb. 19, 2009) (cleaned up) (Mag. J., Opinion, Recommendation and Order), *affirmed and adopted*, 2009 WL 10680297 (M.D.N.C. Sept. 29, 2009)), and is instead "cogent and at least as compelling as any opposing inference one could draw." *Tellabs*, 551 U.S. at 324.

V. Analysis

A. Section 10(b) Claims

Mr. Fisher's claims center around his assertion that the defendants misled investors about Fennec's ability to achieve approval from the FDA for its second New Drug Application for Pedmark from late May through November 2021. Fennec, he alleges, misled investors "by knowingly or recklessly failing to disclose known material deficiencies related to its third-party drug manufacturer," PII, Doc. 24 at ¶ 3, and by

making "materially false and misleading statements" about (or failing to disclose) these manufacturing deficiencies and their investigation into PII's efforts to cure those deficiencies. *Id.* at ¶ 12.

To adequately plead a cause of action based on these general assertions, Mr. Fisher must allege (1) facts that identify with particularity actionable false or misleading statements or omissions, and (2) facts giving rise to a strong inference that the defendants made the statements or omissions with an intent to deceive, manipulate, or defraud. *See supra* pages 8–9. And to be actionable, a statement or omission must be (1) factual, (2) false (or, in the case of omissions, it must render public statements misleading), and (3) material. *Hirtenstein v. Cempra, Inc.*, 348 F. Supp. 3d 530, 553 (M.D.N.C. 2018), *aff'd sub nom. Janies v. Cempra, Inc.*, 816 F. App'x 747 (4th Cir. 2020) (unpublished).

For Mr. Fisher to meet the falsity requirement, he must allege facts that show that at the time the statements were made or omitted:

- PII did not take adequate steps to correct the manufacturing deficiencies identified in the 2020 CRL and did not follow good manufacturing practices from May through November 2021;
- those manufacturing deficiencies at PII were serious enough to impede FDA approval;
- the defendants knew about those deficiencies, knew PII was not taking adequate steps to correct them, and knew that those deficiencies were so serious they were likely to cause problems with the NDA, *or* the defendants recklessly took no steps to verify PII's corrective efforts;

- despite this knowledge, or in reckless disregard of the truth, the defendants made generally positive statements about approval of the NDA; and
- despite this knowledge, or in reckless disregard of the truth, the defendants failed to disclose the problems with the manufacturing facility.

He must also allege facts to show that the defendants acted with an intent to deceive, manipulate, or defraud. *See Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 319 (2007).

The allegations of the complaint show that Fennec made generally positive statements about approval of its NDA from May 28 until September 29, the date Mr. Fisher alleges Fennec became aware of the FDA inspection results, after which the statements became somewhat less positive and more qualified. For the statements preceding September 29, the allegations do not lead to a strong inference of falsity, much less scienter.

The announcement that the company had resubmitted the NDA to the FDA for approval, a fact Mr. Fisher appears to admit is true, is insufficient to show any misrepresentation or material omission at all. No reasonable investor would read this as an implicit representation that the FDA had no problems with the manufacturing facility or that Fennec was guaranteeing the plant would meet FDA criteria. Mr. Fisher points to no other statements or omissions in these early statements that give rise to a strong inference of scienter. And general statements that Fennec expected or hoped for approval are forward-looking statements shielded by the PSLRA's safe harbor provision. *See Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 591 (dismissing claims despite

forward-looking statements made that a drug would receive approval when it eventually did not).

The fact that Fennec knew PII had had manufacturing issues five years earlier and again when the first Pedmark NDA was submitted does not give rise to a strong inference that it had not undertaken efforts to resolve those issues by the spring and summer of 2021. Even if one could infer that the deficiencies were ongoing, Mr. Fisher has not alleged any facts tending to show that the defendants were aware of those deficiencies at the time they made the statements in May, June, August, and early September. And even if one could infer that knowledge after the first FDA inspection perhaps as early as July 26, he has not alleged any facts tending to show that the defendants knew the deficiencies were so serious that they were likely to cause serious problems for the NDA. The fact that the FDA later found those deficiencies to be serious is not sufficient to give rise to a strong inference that Fennec and the individual defendants acted with intent to deceive.

Mr. Fisher faults Fennec for not itself auditing PII's manufacturing procedures or inspecting PII's facilities, *see* Doc. 24 at ¶¶ 8, 66, both of which he says would have led to knowledge of PII's manufacturing problems. While he arguably alleges that no one at Fennec inspected the plant after the July 2020 CRL through January 2021, *id*. at ¶ 66, he has no specific allegations directed to whether Fennec did or did not inspect the plant in the four months after January 2021 leading up to the resubmission of the NDA or over the course of the summer and fall. And elsewhere, inconsistent with his allegation of no oversight, he alleges that the defendants were in direct and continuous communication with PII concerning Pedmark's manufacturing and PII's plan to address deficiencies

identified in the 2020 FDA inspection, *id*. at ¶¶ 6, 58–61, and were highly incentivized to keep close tabs on PII because FDA approval of Pedmark was important to the company. *Id*. at ¶¶ 115, 117.

Mr. Fisher also points to the August 11 statements by Mr. Raykov that manufacturing deficiencies had been addressed and that Fennec's "quality department" believed the facility was ready for resubmission, contending that these were not true statements. *See id*. at ¶¶ 89–92. As with other assertions, however, he points to no facts supporting an inference that Mr. Raykov and Fennec did not believe the deficiencies had been addressed. And he alleges no facts tending to support an inference that other statements made by Mr. Raykov about PII were untrue—for example, that PII had made significant capital improvements and brought in new leadership and additional employees. As noted *supra*, he himself alleges that Fennec was in continuous communication with PII, *id*. at ¶¶ 6, 58–61, and he points to no facts tending to show that PII had not made improvements, even if they later turned out to be inadequate.

Finally, the statement itself does shows an absence of intent to deceive. Mr. Raykov also told investors that Fennec had a back-up plan for another manufacturer if it turned out not to be the case that the plant passed muster, *id*. at ¶ 91, signaling that this was a possibility. He also affirmatively disclaimed providing any "details about the pre-approval proof of inspection because you create expectations." *Id*.

The situation shifts somewhat on September 29, when Mr. Fisher alleges that Fennec received a copy of the EIR and the Form 483 that identified problems with the manufacturing plant, but the needle does not move up to the "strong inference" point.

There are no allegations that the kinds of deficiencies listed in these two forms are the kind that always, or even almost always, lead to CRLs or non-approval, no allegations that anyone at the FDA told or intimated to Fennec that approval was unlikely; no allegations that anyone at PII told Fennec that the problems were of a kind likely to lead to a CRL; and no allegations that anyone at Fennec made statements tending to show they knew a CRL was forthcoming. And Fennec's statements themselves, on their face, become more qualified about approval on and after that date, with a second specific mention of contingency plans should PII fail preapproval inspection, tending to show an absence of intent to deceive. *Id.* at ¶ 96.

Even if one might plausibly infer that once Fennec received the EIR and Form 483 it knew that approval was unlikely and deliberately withheld that information, that inference is not more plausible than the competing inferences that the defendants innocently or negligently failed to realize these facts and their hopeful statements were merely incorrect, not made with the intent to deceive. *See Chapman v. Fennec Pharms. Inc.*, No. 20-CV-812, 2021 WL 7209981, at *14 (M.D.N.C. Dec. 16, 2021) (Mag. J., Order and Recommendation), *adopted* 2022 WL 613378 (M.D.N.C. Mar. 2, 2022); *see also In re Novan, Inc.*, No. 17-CV-999, 2018 WL 6732990, at *5 (M.D.N.C. Nov. 30, 2018) (scienter allegations based on allegation that defendants should have monitored their drug's clinical trials more closely were not sufficient to plead scienter because "[t]he facts as a whole more plausibly suggest that Defendants were acting innocently or negligently rather than deliberately misreporting material information or recklessly

disregarding the truth") (Mag. J., Opinion and Recommendation), *aff'd* No. 17-CV-999, Doc. 65.

Finally, Mr. Fisher points to Fennec's statements about having another back-up manufacturer on board as misleading, but he does not identify any facts that support the inference that this statement was untrue, other than the fact that no new NDA had been filed as of the date of the complaint. To the extent he contends Fennec omitted facts about difficult regulatory hurdles it would face in switching manufacturers, the complaint itself showed that Fennec explicitly acknowledged the switch would cause a delay. Doc. 24 at ¶ 96.

The complaint contains multiple conclusory statements that the defendants acted knowingly or recklessly, *id.* at ¶¶ 3, 29, 131, but such conclusory allegations are insufficient. *See Chapman*, 2021 WL 7209981, at *13; *see also Krim v. Coastal Physician Grp., Inc.*, 81 F. Supp. 2d 621, 632 (M.D.N.C. 1998), *aff'd*, 201 F.3d 436 (4th Cir. 1999) (per curiam) (unpublished). Perhaps the factual allegations support an inference of negligence, but they do not give rise to a strong inference that the defendants acted with an "intent to deceive, manipulate, or defraud" that is "at least as compelling as any opposing inference one could draw." *Tellabs*, 551 U.S. at 319, 324.

B. Section 20(a) Claims

"Section 20(a) of the Exchange Act imposes liability on each person who controls any person liable under any provision of this chapter or of any rule or regulation thereunder." *KBC Asset Mgmt. NV v. DXC Tech. Co.*, 19 F.4th 601, 614 n.4 (4th Cir. 2021) (cleaned up); *accord* 15 U.S.C. § 78t(a). The defendants' § 20(a) liability hinges

on their § 10(b) liability, and Mr. Fisher's "failure to adequately plead a § 10(b) claim dooms" his § 20(a) claim. *KBC Asset Mgmt.*, 19 F.4th at 614 n.4; *see also Chapman*, 2021 WL 7209981, at *15 ("Here, because Lead Plaintiff has failed to state a claim under section 10(b), Lead Plaintiff's 20(a) claims must also fail.").

VI. Motion for Judicial Notice and Consideration

The defendants asked the Court to consider twelve documents, ten as "incorporated by reference" into the complaint and two upon judicial notice. Doc. 27. But they barely refer to these documents in their briefs, nor does Mr. Fisher's complaint rely upon them in any meaningful way. There is no need to consider these documents in evaluating whether the Mr. Fisher's complaint meets the heightened pleading standards of the PSLRA, so the motion is denied.

Similarly, the defendants ask the Court to take judicial notice of a recent FDA press release. Doc. 35. Again, consideration of this document is not needed in evaluating Mr. Fisher's complaint and ruling on the defendants' motion to dismiss, so the motion is denied.

VII. Conclusion

Mr. Fisher's allegations, taken as a whole, do not raise a strong inference that the alleged misrepresentations or omissions were in fact false, or that defendants acted with scienter as to any misrepresentation or omission. The motion to dismiss will be granted.

It is **ORDERED** that:

1. The defendants' motion to dismiss the amended complaint, Doc. 25, is **GRANTED**.

2. The defendants' request for consideration and judicial notice, Doc. 28, is **DENIED as moot**.

3. The defendants' second request for judicial notice, Doc. 35, is **DENIED as moot**.

4. Final judgment will be entered as time permits.

This the 12th day of October, 2022.

UNITED STATES DISTRICT JUDGE